

REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed September 8, 2005 ("Office Action") and the Advisory Action dated January 9, 2006. Claims 1, 3-5, 8-10, and 27-29 are pending in the application. Support for amended claim 1 may be found in original claim 7. Support for amended claim 27 may be found in original claim 10 and at page 5, lines 5-13 of the specification. Applicant respectfully requests reconsideration of the rejection of the pending claims for the following reasons.

STATEMENT OF SUBSTANCE OF INTERVIEW

Applicant hereby submits a statement of substance of interview under 37 C.F.R. § 1.133. An interview between Examiner Cintins and Applicant's representatives Laurence Posorske and Jeff Vockrodt was conducted at the United States Patent and Trademark Office on February 24, 2006. During the interview, the Mehkeri reference was discussed as well as data from the Bustamante Declaration (see below). Agreement was reached during the interview that Mehkeri does not teach any particular particle sizes for its support material. Examiner Cintins stated that support must be found in the specification in order to benefit from the particle size ranges. Applicant agreed to submit data showing that medium size particles have unexpectedly good ability to adsorb *Cryptosporidium* relative to small and large particles.

35 U.S.C. § 112, first paragraph

Examiner Cintins is thanked for withdrawing the rejection under 35 U.S.C. § 112, first paragraph in the Advisory Action dated January 9, 2006.

Obviousness -- 35 U.S.C. § 103

The Office Action rejects claims 1, 3-10, and 27 under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,512,491 ("Mehkeri").

"To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." Manual of Patent Examining Procedure § 2143.03 (8th ed., rev. 2, May 2004) "When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness." M.P.E.P. § 2144.08.

Mehkeri discloses ultra-trace level analysis of water using a coated CELITE (a diatomaceous earth product) support material. Mehkeri, col. 4, ll. 58-67. Coating is accomplished by providing CELITE as a support "upon whose surfaces have been deposited, preferably, a thin layer of freshly-prepared aluminum hydroxide." Mehkeri, col. 3, ll. 7-19. Mehkeri also discloses that "[s]uitable supports include zeolites, kieselghur, fuller's or diatomaceous earth, alumina and silica gel." Mehkeri, col. 3, ll. 9-12. Although Mehkeri states that CELITE is moderately directly effective, it does not state that alumina is effective without coating. Moreover, Mehkeri suggests that alumina will perform in a superior manner only if coated with aluminum hydroxide. Mehkeri teaches that CELITE in particular will trap bacteria and protozoa (including cryptosporidium), Mehkeri, col. 11, ll. 8-15, but fails to teach doing so with hydrated alumina as claimed. Finally, Mehkeri treats alumina identically with silica and thus fails to recognize the benefits of using hydrated alumina to remove Cryptosporidium from water as claimed.

The Office Action recognizes certain differences between the claims and the teachings of Mehkeri, but concludes that it would have been obvious to modify Mehkeri to "dispense with the additional aluminum hydroxide coating suggested by the reference, and to contact the water undergoing treatment directly with the surface of the hydrated alumina, if one were willing to forgo the advantages associated with this additional coating." Office Action, page 3. This reasoning fails to set forth a prima facie case of obviousness because the Office Action never gives a reason why a person of ordinary skill in the art at the time of the invention would be "willing to forgo the advantages associated with this additional coating." "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of

ordinary skill in the art.” M.P.E.P. § 2143.01.I. Furthermore, the teachings of Mehkeri run counter to the claimed invention by stating that a coating of material should be used rather than the uncoated support material. “It is improper to combine references where the references teach away from their combination.” See M.P.E.P. § 2145.X.D (quoting In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). The obviousness rationale fails to provide any motivation for practicing the claimed invention and indeed proceeds contrary to the express teachings of Mehkeri. Accordingly, the rejection of claims 1, 3-10, and 27 under 35 U.S.C. § 103 as being obvious over Mehkeri must be withdrawn.

Unexpected Results

“When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a prima facie case of obviousness.” M.P.E.P. § 2144.08. “Evidence of unexpected results must be weighed against evidence supporting prima facie obviousness in making a final determination of the obviousness of the claimed invention.” M.P.E.P. § 716.02(c).I (quoting In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)).

Removal of Cryptosporidium with Hydrated Alumina

Claims 1, 3-5, 8-10, and 29 require, *inter alia*, removal of Cryptosporidium from water comprising the steps of contacting the water with the surface of a surface hydrated alumina (Al_2O_3) medium. Claim 1 reads:

A method for the removal of Cryptosporidium from water comprising the steps of contacting the water with the surface of a surface hydrated alumina (Al_2O_3) medium, which contains a surface density of Al-OH groups sufficient to render the surface of the alumina medium hydrophilic, for a time and under conditions such that a proportion of the Cryptosporidium present in the water are absorbed onto said hydrated alumina medium and removed from the water in a sufficient amount to make the water fit for human use or activity.

The largely irreversible adsorption of Cryptosporidium on surface hydrated alumina is described throughout the specification. See example II, pages 15-17 and Figs. 7 and 8, which compare retention of Cryptosporidium by hydrated alumina relative to silica. Fig. 7 shows that when water containing Cryptosporidium is passed through a filter, there is substantial Cryptosporidium in the permeate and subsequent rinses when the filter is made up of silica. In

contrast, Fig. 8 shows that very little *Cryptosporidium* passes through the filter in the permeate and in subsequent washes when hydrated alumina is used. The Declaration Under 37 C.F.R. § 1.132 of Marilyn Karaman dated March 22, 2002 (“Karaman Declaration”) compares the ability of hydrated alumina to retain *Cryptosporidium* relative to a number of other inorganic solids, including silica. See Karaman Declaration, paragraphs 5-6 and Annex B, Fig. 1. In Figure 1, the Karaman Declaration shows that nearly 100% of the oocysts were eluted after a single washing in a silica column, while less than 20% of the oocysts were eluted after seven washings of a hydroxylated alumina column. The evidence in the specification and Karaman Declaration both show that hydrated alumina significantly outperforms silica in trapping *Cryptosporidium*. In contrast, Mehkeri fails to recognize any specific advantages of selecting hydrated alumina relative to silica or silica based media such as fuller’s earth, diatomaceous earth, and CELITE. The obviousness rejection of claims 1, 3-5, 8-10, and 29 is clearly not sustainable in view of the foregoing evidence indicating the unexpected property of hydrated alumina being capable of enhanced adsorption of *Cryptosporidium* oocysts. Accordingly, the rejection of claims 1, 3-5, 8-10, and 29 under 35 U.S.C. § 103 as being obvious over Mehkeri should be withdrawn.

Particle Sizes in the Range of About 0.05 mm to about 1.5 mm

Claims 10, 27, 28, 29, and 30 require, *inter alia*, removal of protozoa from water by contacting the water with the surface of a surface hydrated alumina, the surface hydrated alumina comprising a particle size of about 1.5 mm to about 0.05 mm. The specification discusses the importance of a similar range (0.5-2 mm) in maximizing collision and capture of biological species by the particles. Specification, page 6, first paragraph. The specification further teaches that in purifying domestic water it would be appropriate to use the smallest particle sizes to both minimize the size of the filter device and achieve maximum surface area while insuring that pressure drops across the filter cartridge containing alumina are minimized. Specification, page 6, second paragraph. Thus, the advantages of the claimed ranges were appreciated in the specification as filed.

Mehkeri does not disclose any particle sizes for any of the supports discussed. The Declaration Under 37 C.F.R. § 1.132 of Heriberto Alejandro Bustamante dated February 7, 2006 (“Bustamante Declaration”) shows the effect of particle size on oocyst removal. Specifically, the Declaration shows that medium size particles provide reasonable removal of oocyst using gravity

alone. In addition, the Bustamante Declaration demonstrates between 2.5 and 3.5 log oocyst reduction for hydrated alumina compared to 0.6 log reduction when using medium sized sand particles. It is noted that diatomaceous earth media relies primarily on physical filtration and requires a much smaller particle size to be effective than hydrated alumina. Thus, diatomaceous earth media requires higher pumping pressures and reduced flowrates. The evidence presented in the Bustamante Declaration shows that good removal of *Cryptosporidium* can be achieved using pressure produced by gravity alone. This result cannot be predicted by reference to prior art such as Mehkeri. Accordingly, the rejection of claims 10, 27, 28, 29 and 30 under 35 U.S.C. § 103 as being obvious over Mehkeri should be withdrawn.

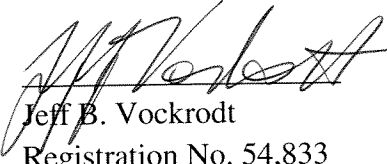
Conclusion

Independent claims 1 and 27 are patentable over Mehkeri. The Karaman Declaration, which is addressed primarily toward the invention of independent claim 1, shows the unexpected results obtained by using hydrated alumina to remove *Cryptosporidium* from water. The Bustamante Declaration, which is directed primarily toward the invention of independent claim 27, shows unexpected properties of the claimed particle size range. It is noted that both results are applicable to claim 10, which includes the particle size limitation and is dependent upon claim 1. Applicant respectfully request consideration of the evidence in relation to each of the claims in this application.

Applicant submits that this response addresses all of the issues raised in the Office Action and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. In the event any variance exists between the amount authorized to be charged to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
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